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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,712	08/25/2000	Peter Nawroth	8484-075-999	7074

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EXAMINER
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QIAN, JANICE LI

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,712

Applicant(s)

NAWROTH ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-21,23-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-17,20,21,23-28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment and response filed Oct. 20, 2003 have been entered. Claim 29 has been canceled. Claims 7, 13, 14, 17, 20, 21, 30-32 have been amended. Claims 18 and 19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 7-17, 20, 21, 23-28, and 30-35 are under current examination.

This application contains claims (18, 19) drawn to an invention nonelected without traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

Previous objection of claims 7-17, 20, 21, 23-28, 30-35 is withdrawn in view of claim amendment.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-17, 20, 21, 23-28, and 30-35 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *activating* blood vessel

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formation or enhancing wound healing in a subject in need comprising administering a nucleic acid expressing the Tissue Factor (TF) locally, wherein the nucleic acid is a plasmid vector comprising a constitutive promoter, does not reasonably provide enablement for activating blood vessel formation or enhancing wound healing in a subject in need comprising *inducing* local expression of a TF by *any* means or locally administering *any* type of nucleic acid comprising an inducible promoter operably linked to a TF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

With respect to the type of nucleic acids encompassed by the claims, applicants cited other published references using an adenoviral vector as support for the enablement of the instantly claimed invention. The argument is not persuasive because the claims are much broader than using adenoviral vectors; they are contradictory to the teaching of the specification as cited in the previous action; and the cited references are not expressing TF, thus, the efficiency of expressing TF, consequently whether a therapeutic levels of TF expression could be achieved is unpredictable. It is further noted that claims excluding expression of TF in malignant tissue (see claims 7 & 20), yet the response cited numerous references expressing viral vectors in malignant cancer tissue (paragraph bridging pages 13 & 14). Apparently, these references fail to support what is now claimed.

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With respect to the effect of TF, the specification teaches TF activates blood vessel formation; yet, the claims recite "modulating blood vessel formation", which encompasses both activating and reducing blood vessel formation.

With respect to inducing local expression of a Tissue Factor nucleic acid, applicants argue in the 10/20/03 response that inducible promoter is well known in the art at the time. However, as indicated in pages 6-7 of paper #23, the claims are much more broader than using an inducible promoter, they encompass multiple means of inducing local TF expression, and the specification fails to teach means other than using an inducible promoter, thus fails to support the full scope of the claims. 35 U.S.C. § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In re Fisher, 166 USPQ 18, 24 (CCPA 1970). Moreover, as cited previously as taught by Miller et al, the inducible and tissue-specific promoters often loss their appropriate function due to the cellular environment, particularly in the presence of a strong endogenous promoter. The specification fails to teach how to overcome the art-known hurdles, and it would have required undue experimentation for the skilled artisan intending to practice the instant invention.

For the reasons of record and those set forth above, the instant specification fails to meet the enablement provision set forth under 35 U.S.C. §112, 1<sup>st</sup> paragraph.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942 (571-272-0730, after the Office relocation in January, 2004). The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Q. Janice Li  
Patent Examiner  
Art Unit 1632

*QJL*  
January 8, 2004

**ANNE M. WEHBE, Ph.D.**  
**PRIMARY EXAMINER**

*Allen*